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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,130	06/22/2000	MICHAEL JOHN DUGGAN	1581.0580000	2901

7590 07/07/2003  
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EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/07/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/529,130

Applicant(s)

DUGGAN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-12,14,20-41,44-47,50-54,57 and 63-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63-70 is/are allowed.
- 6) ☒ Claim(s) 1,4-12,14,20-41,44-47,50-54 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 4-12, 14, 20-41, 44-47, 50-54, 57 and 63-70 are pending.

Applicants' amendment filed on April 25, 2003 (Paper No. 20) is acknowledged, and applicants' response has been fully considered. Claim 57 has been amended, claims 13, 15, 16, 18, 19, 42 and 43 have been cancelled, and new claims 63-70 have been added. Thus, claims 1, 4-12, 14, 20-41, 44-47, 50-54, 57 and 63-70 are examined.

2. The first page of PTO-1449 filed September 10, 2002 (Paper No. 16) is attached.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claim 57, under 35 U.S.C. §112, first paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 5 in Paper No. 20.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4-12, 14, 20-41, 44-47, 50-54 and 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Foster *et al.* (WO 96/33273) taken with Sharon *et al.* (The FASEB Journal 4, 3198-3208 (1990)).

Foster *et al.* teach an agent containing lectin (page 13, lines 9-13) as the targeting moiety (TM) and a modified clostridial neurotoxin such as LH<sub>N</sub> (including L-chain and its functional fragment, claims 1, 24-31, 35, 39, 46, 50), the clostridial neurotoxin having H<sub>C</sub> chemically modified to reduce its ability to bind the receptor (claims 20-23, 36), and a hybrid molecule of a modified heavy chain (H<sub>C</sub> being modified) of a clostridial toxin with a light chain of a different clostridial toxin (page 13, line 18-page 14, line 19; claims 32-34) can be obtained by covalently attachment of a TM to a modified clostridial neurotoxin using linkage including one or more spacer regions (page 14, lines 1-9; claim 37, 40, 47) or can be expressed recombinantly as a fusion protein (page 14, line 29-page 15, line 4; claim 38, 41, 50). This agent can bind to a binding site on the surface of sensory neurons (page 12, lines 25-28) and reduce or preferably prevent the transmission of pain signals from nociceptive afferents to projection neurons (page 7, lines 15-17; claims 44-45), therefore it can be used for controlling the transmission of sensory information or pain signals from a nociceptive afferent to a projection neuron (claims 51-54 and 57). However, Foster *et al.* do not disclose using a specific lectin such as galactose-binding lectin in preparing the agent. Sharon *et al.* teach certain oligosaccharides such as complexed type oligosaccharides with terminal galactose residues can act as multivalent ligands that cross-

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link and precipitate galactose or N-acetylgalactosamine specific lectins such as soybean agglutinin, or those of different Erythrina species (page 3200, right column; Table 1; claims 4-12), and the S-type lectins in animals that have a specificity for  $\beta$ -galactosides (page 3198, right column; claim 14). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to make the agent taught by Foster *et al.* and to use the specific lectin such as galactose-binding lectin taught by Sharon *et al.* because the galactose-binding lectins are widely available in legume plants (see Table 1 of Sharon *et al.*), can bind multivalent oligosaccharides having terminal galactose residues more specifically, and serve as a cell-recognition molecule for the agent. Thus, the combined references result in the claimed invention and were, as a whole, *prima facie* obvious at the time the claimed invention was made.

In response, applicants indicate the combined references of Foster *et al.* and Sharon *et al.* do not establish a *prima facie* case of obviousness because the primary reference, Foster *et al.*, do not disclose the use of a specific lectin such as galactose-binding lectin in preparing the agent, and this deficiency is not cured by the secondary reference, Sharon *et al.* Applicant further indicate that the two assertions, "the galactose-binding lectins are widely available in legume plants (see Table 1 of Sharon *et al.*)", and "can serve as a cell-recognition molecule for the agent" made by the Examiner, do not show a suggestion, teaching or motivation to combine the prior art references to establish a *prima facie* case of obviousness; and that Sharon *et al.* teach lectins, including legume lectins are currently attracting much interest, primarily because they serve as invaluable tools in diverse areas of biological and medical research, and the reference also indicates lectins can serve as cell recognition molecules, however, Sharon *et al.* do not explain to what the important implications of this research might be, nor teach or suggest the use

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of purified lectins as a portion of a larger, non-natural, biologically active agent (pages 6-11 of the response). The response have been fully considered, however, the argument is not found persuasive because Sharon *et al.* teach "oligosaccharides such as complexed type oligosaccharides with terminal galactose residues can act as multivalent ligands that cross-link and precipitate galactose or N-acetylgalactosamine specific lectins, and the specificity of interactions of lectins with these multivalent oligosaccharides is greater in the formation of cross-linked complexes than in that of non-cross-linked ones. These results have important implications for the biological functions of cell surface receptors for lectins." (page 3200, col. 2; paragraph bridged pages 9 and 10 of the response), which suggests the specific binding of galactose-binding lectins to complexed type galactose-containing oligosaccharides can be implied to the binding of lectin to the cell surface receptors, which is the motivation to use galactose-binding lectins in the agent for targeting receptors on the cell surface. Therefore, the combined references of Foster *et al.* and Sharon *et al.* establish a *prima facie* case of obviousness.

### ***Conclusion***

6. Claims 1, 4-12, 14, 20-41, 44-47, 50-54 and 57 are rejected, and claims 63-70 are free of art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

*Christopher S. F. Low*

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July 5, 2003